

DENTIN HYPERSENSITIVITY MANAGEMENT

A Clinical Study Investigating The Efficacy Of A Desensitizing Dentifrice

Raquel Sofia Brandão de Carvalho

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Author:

Raquel Sofia Brandão de Carvalho ¹

¹⁵th year Student of Dental Medicine at the Faculty of Dentistry, University of
Porto

E-mail: mimd12018@fmd.up.pt or raquelsbcarvalho@gmail.com

Supervisor: PhD Paulo Rui Galvão Ribeiro de Melo

Associate Professor of the Faculty of Dentistry, University of Porto

"Strive not to be a success, but rather to be of value"

Albert Einstein

"Great things are done by a series of small things brought together"

Vincent Van Gogh

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Abbreviation List

Adverse Events - **AEs**

Dentin Hypersensitivity – **DH**

Nano-hydroxyapatite – **n-HA**

Potassium Chloride - **KCl**

Schiff Cold Air Sensitivity Scale – **SCASS**

Standard Deviation – **SD**

Visual Analogue Scale – **VAS**

Abstract

Introduction: Dentin Hypersensitivity is a frequently reported distressing oral condition ranging from mild to unbearable pain. Although variable, predominantly appears as a transitory acute pain caused by several stimuli and it cannot be attributed to any other dental conditions than gingival recession, tooth erosion, abrasion and/or abfraction. The control of symptomatology should, firstly, focus on preventive strategies and subsequently direct the therapy with the objective of interfering, transiently or permanently, on its pain mechanism.

Objective: To evaluate the short-term effectiveness of a nano-hydroxyapatite (7,5%) based desensitizing dentifrice compared to a fluoridated toothpaste on the reduction of dentin hypersensitivity.

Methods: This was a double blind, randomized, parallel-group, 4-week study in healthy adults with self-reported and clinically diagnosed dentin hypersensitivity. Thirty subjects with at least two eligible teeth were randomly distributed to one of the two experimental groups and instructed to brush twice daily with the allocated toothpaste. Tooth sensitivity was assessed at baseline, after 2 and 4-weeks of treatment in response to evaporative (air-blast) and thermal (ice) stimuli measured by visual analogue scale. Data collected at all evaluations was then compared using the Wilcoxon test and further analysis was performed with the U Mann-Whitney test and the Bonferroni correction.

Results: All 30 participants completed the clinical study and the results obtained confirm that for both treatments there was a statistically significant reduction on dentin hypersensitivity throughout the 4-week observation period. No statistical or clinical

differences amongst the two therapies were demonstrated for the two pain assessments at the end of the study, with exception to the response of the evaporative stimuli at baseline, where there was a statistically significant difference between the experimental groups.

Conclusions: The performance of the two dentifrices was similar after the 4-week treatment time demonstrating identical benefits concerning tooth sensitivity on short-term basis as they both seem to be clinically capable of and effective in reducing dentin hypersensitivity.

Key-words

*"Dentin hypersensitivity", "dentine occlusion", "treatment dentin hypersensitivity",
"nano-hydroxyapatite" and "dentin sensitivity etiology"*

Resumo

Introdução: A Hipersensibilidade Dentinária é uma condição oral dolorosa comumente citada na prática clínica que varia de dor leve a insuportável. Embora variável, surge predominantemente como uma dor aguda de curta duração transitória provocada por diversos estímulos e não pode ser atribuída a outras condições dentárias que não a recessão gengival, erosão dentária, abrasão e/ou abfração. O controlo da sintomatologia deve, numa primeira fase, apostar em estratégias preventivas e, posteriormente, dirigir a terapia com o objetivo de interferir, transitória ou permanentemente, no seu mecanismo de dor.

Objetivo: Avaliar a eficácia a curto prazo de um dentífrico dessensibilizante constituído por nano-hidroxiapatite (7,5%) em comparação com uma pasta dentífrica fluoretada (placebo) sobre a redução na hipersensibilidade dentinária.

Metodologia: Estudo duplamente cego, randomizado, em grupo paralelo, com duração de 4 semanas em adultos saudáveis autodiagnosticados e confirmados clinicamente detentores de hipersensibilidade dentinária. Trinta indivíduos com pelos menos dois dentes elegíveis foram distribuídos aleatoriamente num dos dois grupos experimentais e instruídos a escovar duas vezes por dia com a pasta dentífrica selecionada. A sensibilidade foi avaliada na *baseline* e após 2 e 4 semanas de tratamento, em resposta a estímulos evaporativos (ar) e térmicos (gelo), medidos por uma escala visual analógica. Os dados recolhidos em todas as avaliações foram, então, comparados através do teste Wilcoxon tendo-se, posteriormente, recorrido ao teste U Mann-Whitney com a correção de Bonferroni.

Resultados: Todos os 30 participantes completaram o estudo clínico sendo que os resultados obtidos confirmaram que, para ambos os tratamentos, houve uma

redução estatisticamente significativa da hipersensibilidade dentinária ao longo do período de observação de 4 semanas. Não foram demonstradas diferenças estatísticas ou clínicas entre as duas abordagens terapêuticas para as duas avaliações de dor no final do estudo, com exceção da resposta aos estímulos evaporativos na *baseline*, onde houve diferença estatisticamente significante entre os grupos experimentais.

Conclusões: Os dois dentífricos atuaram de forma semelhante, no intervalo de 4 semanas de tratamento, demonstrando benefícios idênticos no que concerne à sensibilidade dentária a curto prazo, uma vez que ambos parecem ser clinicamente capazes e eficazes na redução da hipersensibilidade dentinária.

Palavras-chave

"Hipersensibilidade dentinária", "oclusão dentinária", "tratamento hipersensibilidade dentinária", "nano-hidroxiapatite" e "etiologia sensibilidade dentinária"

I. Introduction

Dentin Hypersensitivity (DH) is a frequently reported painful oral condition that affects the oral comfort and function amongst patients interfering with their quality of life. More often patients accept the discomfort caused by this complaint and commonly fail to inform and seek help. For that reason DH is also one of the least predictably and successfully treated chronic problem in dentistry ⁽¹⁻³⁾.

Pain arising from DH may be variable in character and intensity but it is usually described as a short or transient episode of sharp and well-localized pain which arises from exposed dentine tubules due to aetiological factors such as gingival recession, dental erosion, abrasion and/or abfraction in response to typically thermal, evaporative, mechanical/tactile, osmotic or chemical stimulation, and cannot be attributed to any other form of dental defect, disease or pathology ⁽⁴⁻⁶⁾. The reported prevalence of DH differs widely and ranges from 4% to 57% in the general population ⁽⁷⁻¹⁰⁾. Therefore, in order to obtain a correct diagnosis, all other pathologies that may elicit the same clinical symptoms must be excluded.

Its pathogenesis remains unclear and many hypotheses have been proposed to explain its biologic mechanism, however scientific evidence supports the Hydrodynamic Theory, postulated by Gysi in 1900 and reinforced by Brännström in 1963 ^(1, 11-13). According to the principles of the hydrodynamic theory, a hyperesthesia results from pain-provoking stimuli when contacting exposed dentine, causing changes of the fluid flow inside the dentinal tubules. This activates the baroreceptors leading to a neural signal to the pulp and may, if certain physiological parameters are met, generate a pain response ^(3, 4, 6, 14).

Consciousness of the patient clinical history combined with the understanding of the pathophysiology of DH are essential in order to better comprehend, prevent and evaluate the best treatment option ⁽²⁾. In the past, DH treatment has been conducted without considering the aetiological factors,

emphasizing the limitations of such an approach. Actually, the management of DH symptomatology should, firstly and ideally, consider preventive strategies, directed towards the aetiology, such as modification of dietary intake, oral hygiene technique and occlusal contacts. After this intervention it should be considered a direct therapy, which aims to interfere whether transiently or permanently with the mechanism described for this condition ^(5, 7).

A vast range of treatment techniques and materials exist for managing DH and according to the mode of delivery can be professionally applied at the clinical office or at home by the patient. In its essence they all fall under two major categories of their mechanisms of action, nerve stabilisation/desensitisation, physical occlusion and/or reduction of the diameter of exposed dentinal tubules ^(6, 7, 11-13, 15). In order to achieve the desired results, the agents used at home include dentifrices, gels and mouthwashes containing fluorides or other desensitizing substances such as potassium salts, formaldehyde, strontium salts, oxalates, and more contemporary materials such as arginine and nano-hydroxyapatite (n-HA). N-HA is considered one of the most biocompatible and bioactive substances – its nano-sized particles may easily diffuse into the dentinal tubules and promote mineralisation – and is used in variable concentrations in several formulated toothpastes ^(1, 16). The treatment modalities used at the office include the application of dentin sealers such as resins, mucogingival plastic surgery and, more recently, the use of laser irradiation ^(5, 12, 13, 15).

Currently, literature presents many clinically beneficial approaches at treating DH, however there has not yet been discovered a technique to be clearly superior to the others in managing this condition ^(2, 11).

This investigation intends to evaluate the short-term effectiveness of a dentifrice with 7,5% n-HA compared to a fluoridated toothpaste – placebo – on DH reduction.

II. Methodology

II.1 Study Design and Participants Recruitment

This study consisted on a 4-week double blind, two treatment, parallel-group, randomised clinical trial in healthy adult patients with self-reported and clinically diagnosed DH. Two groups were enrolled to participate in a treatment plan with (1) "Nano-Hydroxyapatite" based dentifrice (2) "placebo" fluoridated toothpaste. This study was conducted in Oporto, Portugal, at the Dental Clinic of the Faculty of Dental Medicine of the University of Porto after approval by the faculty's ethics committee.

II.2 Inclusion Criteria

Table I – Inclusion Criteria

Aged 18 and over with good oral health
2 or more hypersensitive teeth (criteria is described in the assessment procedure)
No systemic diseases or controlled systemic diseases (e.g. Diabetes)
Availability and interest to collaborate for the duration of the study and to sign an informed consent form
Motivated to reduce DH

II.3 Exclusion Criteria

Table II – Exclusion Criteria

Under 18 years old
Active caries, uncontrolled periodontal disease, untreated fungal and/or tumours oral lesions, extensive/defective restorations, hypersensitivity teeth with significant mobility and post-operative hypersensitivity
Pregnancy or lactation
Uncontrolled systemic diseases or began medication with anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics within one month prior to the start of the study or during the course of the study
History of allergy and/or sensitivity to the test products or their ingredients
Individuals who had participated in any other desensitizing dentifrice study or used a desensitized dentifrice within the last three months
No availability to participate in the study and/or uninterested

II.4 Participants Selection

Volunteered healthy patients with at least two sensitive teeth that met all the criteria at the screening and baseline examination performed at the FMDUP clinic were enrolled onto the study and were randomly allocated to a treatment group by the researcher so that approximately equal number of subjects received each treatment.

II.5 Sample size determination

The target group consisted of all patients that arrived to the FMDUP clinic complaining of teeth sensitivity. The collaboration of 5th and 4th year Dental Medicine Students from the FMDUP clinic was essential for the recruitment and selection of participants. A questionnaire (appendix 3) was applied to 113 patients, between January and April of 2017, in order to assess the presence of DH.

DH was firstly diagnosed by enquiring patients to rate their perception of sensitivity to different trigger stimuli such as thermal, osmotic and mechanical stimulation. Sensitive teeth were identified by the patient's response to air-blast stimulus, applied with a dental air syringe to the exposed buccal surface.

The first 30 prospective participants who met the inclusion/exclusion criteria and signed an informed consent form (appendix 2) were selected. The main investigator assigned a baseline hypersensitivity evaluation – *air-blast and thermal* – along with an oral soft and hard tissue assessment and the patients were requested to answer a survey concerning the pain associated with DH (appendix 4).

At screening, each selected participant was sequentially randomised being allocated with its unique screening assigned number, and then was randomly

appointed to one of the two study treatments: (1) toothpaste “n-HA” (2) toothpaste “Placebo”. Each participant could have two or more teeth selected.

II.6 Test materials

Both products were letter coded and distributed in similar containers in order to maintain the study participants and the examiner unaware of its contents.

Test group A: N-HA based dentifrice (Fluidinova© NanoXIM•CarePaste)

- 7,5% n-HA – to promote dentin tubules occlusion and enamel remineralisation.

Table III – Composition of dentifrice used for Group A treatment

Composition
7,5% nanoXIM.CarePaste (1.16% n-HA) Sorbitol; Aqua; Calcium Carbonate; Hydroxyapatite; Silica; Sodium Laureth – 2 Sulfate; Parfum; Cellulose Gum; Titanium Dioxide; Sodium Saccharin; Triclosan

Test group B: Control group (Placebo)

- Toothpaste with no desensitizing agents.

Table IV – Composition of dentifrice used for Group B treatment

Composition
Sorbitol; Aqua; Calcium Carbonate; Silica; Sodium Laureth – 2 Sulfate; Parfum; Cellulose Gum; Titanium Dioxide; Sodium Saccharin; Triclosan, 1450 ppm F

The two treatment products were used in two sets – office and at home – and were all applied in the same manner.

II.7 Treatment procedure

Following the assignment of the subjects into the two different study groups, the main investigator applied the test materials. To ensure the examiner remained blind, the preparation and dispersal of the blinded study treatments took place in a previous separate area.

II.7.1 Application procedure in Office

- Clean all surfaces to remove excess saliva;
- Application of a pea sized dose of test toothpaste on the cervical dentin of the selected tooth with the fingertip massaging the area for approximately 20 timed seconds, followed by assessment (Figure 1);

Each tooth was treated individually and sequentially.



Figure 1 – Illustration of application procedure

Following topical application and assessment, participants were provided with the same test product (toothpaste with 96 g) for use at home.

II.7.2 Post-application instructions (appendix 6):

- Do not eat or drink for the 30 minutes following the procedure

- Avoid hot drinks, products containing alcohol and sticky or chewy foods for at least 4 hours

II.7.3 Application procedure at Home

Subjects should only use the designated paste during the study.

Each participant was educated to first brush all other areas as their normal oral hygiene routine and then apply the product onto the sensitive teeth and massage for approximately 30 seconds - subjects were instructed to brush only with the nominated paste for two minutes, at least twice daily for the duration of this study.

The post-application instructions were the same as the in-office treatment.

II.7.4 Additional instructions

Subjects were advised to refrain from any other oral hygiene procedures, such as the use of mouthwashes, throughout the duration of the study. In addition, were instructed to refrain from chewing gum for eight hours and from eating and drinking for four hours prior to their follow-up hypersensitivity evaluations. There were not other restrictions regarding diet or smoking habits during the course of the study.

Used toothpaste tubes were collected from participants at the end of the study and product use compliance evaluated by weight. In the occurrence of more test material being required, participants were requested to return to FMDUP clinic to collect additional dentifrice (Figure 2).



Figure 2 – Illustration of some of the collected toothpastes

II.8 Follow-up

Subsequent evaluations were conducted after 2 and 4 weeks of product use at the FMDUP clinic.

In order to appraise the progress of the treatment, all the assessments were conducted in every visit – oral soft and hard tissue examination, as well as, air-blast and thermal response evaluations. In addition, the *Dentin Hypersensitivity Survey* (appendix 4) was given out to assess the management of this condition. The examiner did not hold the previous responses to the cited survey as it was kept secret by the researcher, so that the patient's feedback and/or the examiner's approach would not be persuaded in any way and also, to enable the comparison of all responses at the end of this investigation.

II.9 Assessments

Two outcome (pain) measures – *Air-Blast* and *Thermal* evaluations – were used at enrolment, baseline visit before and after application, and at the designated follow-up dates.

II.9.1 Hypersensitivity assessments

Air-Blast sensitivity assessment:

- Isolation of the sensitive tooth from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the neighbouring teeth (Figure 3);
- Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 19 °C (± 5 °C) directly at the exposed buccal surface for 3 seconds and from a distance of approximately 1 cm (Figure 4);
- Two response measures were taken, a subjective assessment utilising a visual analogue scale (VAS) (Figure 5) and an examiner-based Schiff assessment.

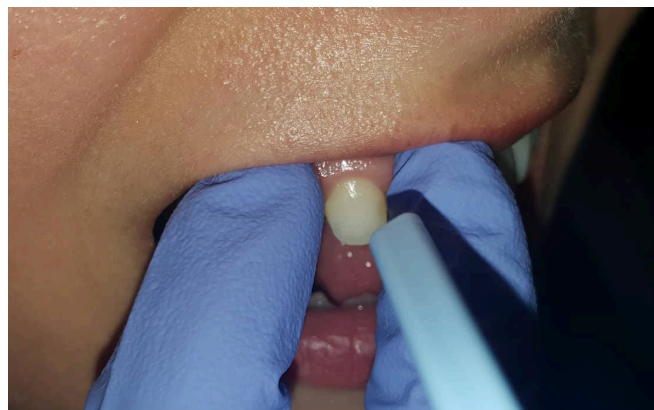


Figure 3 – Illustration of air-blast assessment procedure

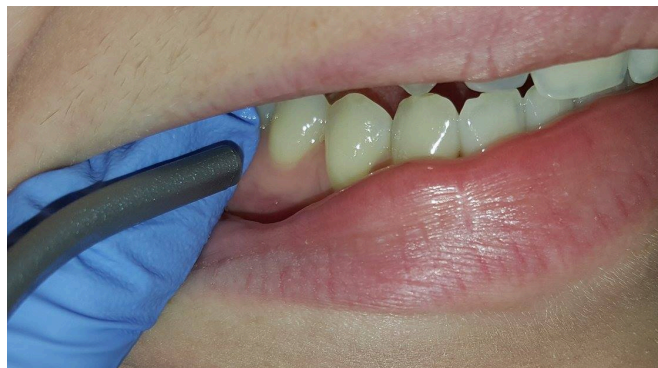


Figure 4 – Illustration of air-blast assessment procedure (distance of approx. 1 cm.)

VAS

Subjects were asked to rate the intensity of their response to the stimulus from no pain to intolerable pain.



Figure 5 – Visual Analogue Scale

Schiff Cold Air Sensitivity Scale (SCASS)

0 – Subject does not respond to air stimulus

1 – Subject responds to air stimulus, but does not request discontinuation of stimulus

2 – Subject responds to air stimulus and requests discontinuation or moves from stimulus

3 – Subject responds to air stimulus, considers stimulus to be painful and requests discontinuation of the stimulus

Subjects with scores of 2 or 3 present and measured at the baseline examination were included in this study.

Thermal sensitivity was assessed in the following manner:

- Application of ice-cold water to the exposed dentin surface while adjacent teeth were isolated during testing using cotton rolls (Figure 6).
- Sensitivity was measured using a VAS (Figure 5). Subjects were asked to rate the intensity of their response to the stimulus from no pain to intolerable pain.



Figure 6 – Illustration of thermal assessment procedure

Subjects with scores greater than 5 present and measured at the baseline examination were included in this study.

If both baseline scores – *air-blast* and *thermal* – were met by the participant it would verify its eligibility hence the individual would be qualified for participation.

II.9.2 Clinical Assessment

To determine eligibility, oral soft and hard tissue examinations were performed in all participants, in order to verify if any of the exclusion criteria was present, such as dental mobility.

The examiner assessed the oral cavity and peri-oral area using a dental light and mirror. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands and the tonsillar and pharyngeal areas.

All assessments were performed by the same examiner and conducted at enrolment, baseline and designated follow-up dates.

II.10 Adverse Events

The main investigator interviewed, in every visit, the subjects in order to acquire any report of adverse events (AEs) and the use of concomitant medications.

All observed or subject-reported AEs, regardless of treatment group, were recorded. AEs were monitored from the time that the subject provided informed consent, which was prior its participation in this study, up to including 7 days after the last administration of the investigational product.

II.11 Statistical Analysis

Results were recorded and subjected to statistical analysis. Intending to depict de study sample, descriptive analysis was performed in which quantitative data was described by the calculation of the mean and standard deviation (SD) and qualitative variables were compared using the Chi-Square analysis.

In regard to the efficacy evaluation, the non-parametric Friedman test was performed to compare the raw means of air-blast and thermal hypersensitivity scores of the two different regiments at baseline, 2 and 4 weeks of product use. The results were then compared using the Wilcoxon and the U Mann-Whitney tests considering, simultaneously, the Bonferroni correction.

In order to perform the data analysis the software utilized to register all the collected data was the *Microsoft® Excel®* for Mac (2011 Version 14.7.3, 2010 ©Microsoft Corporation, Redmond, Washington, USA), and for the statistical analysis the *SPSS® (Statistical Package for the Social Science, IBM SPSS Statistics for Macintosh Version 24.0. Armonk, NY: IBM Corp.)* employing the statistical significance set at $\alpha=0,05$ for all tests.

III. Results

III.1 Subject Demographic and Baseline Characteristics

A total of 113 subjects were interviewed between January and April, in order to assess for eligibility to participate in the trial, of whom 30 met the necessary inclusion/exclusion criteria and were randomly assigned to the two study groups. All subjects complied with the protocol and completed the 4-week clinical study. An outline of the progression of the clinical trial is shown in Figure 7.

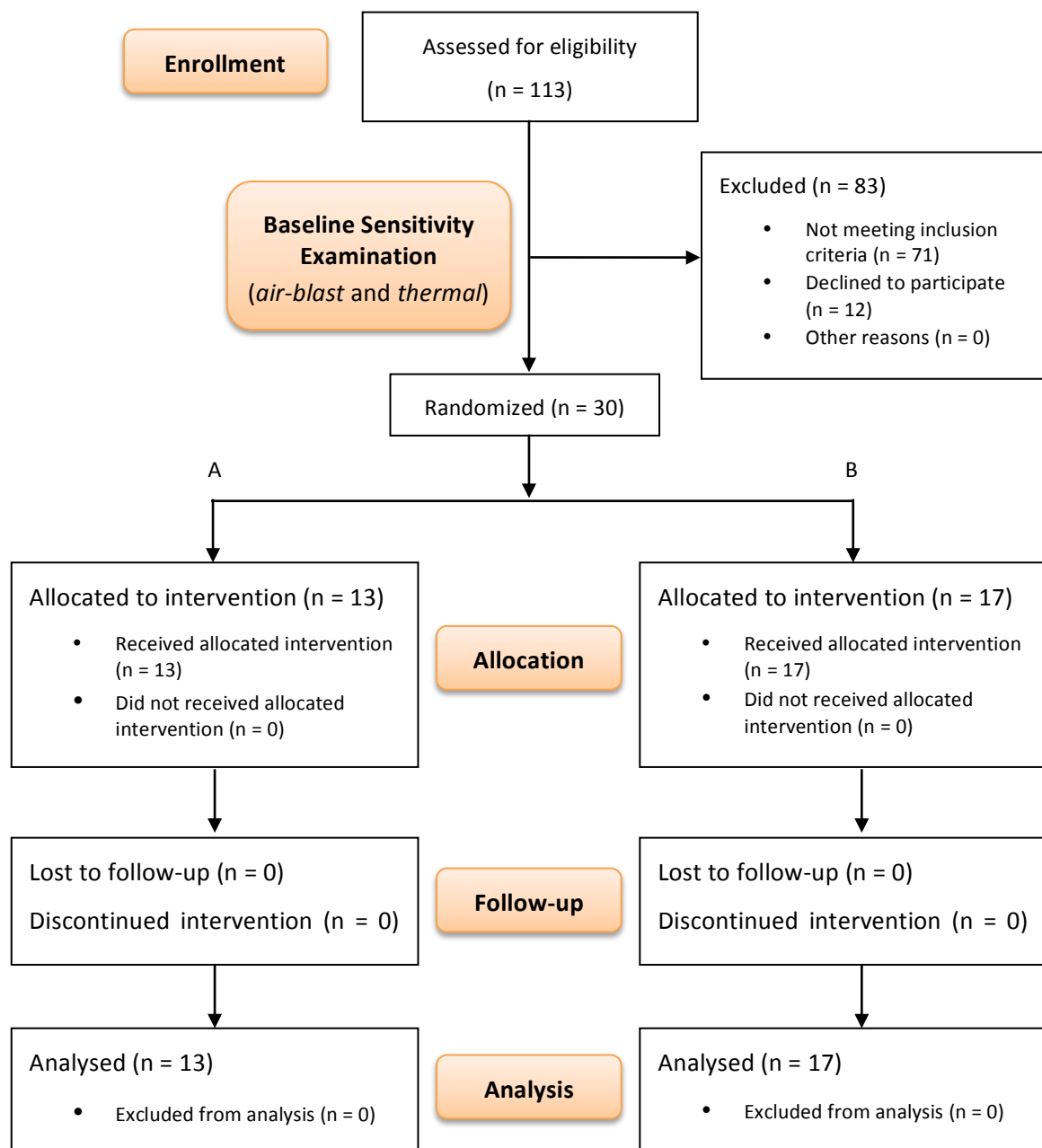


Figure 7 – Flowchart of participants throughout each stage of the study

The study entailed 30 individuals, 13 (43,3%) enrolled on group A and 17 (56,7%) on group B. All study participants were Caucasian between 21 and 70 years old (mean age 31.66 ± 13.24 years) and it involved 5 males (16,7%) and 25 females (83,3%). The age group the highest occurrence of DH was the 18-24 years old (Figure 8). The treatment groups did not differ significantly with respect either to age ($p > 0,284$) or to gender ($p > 0,070$).

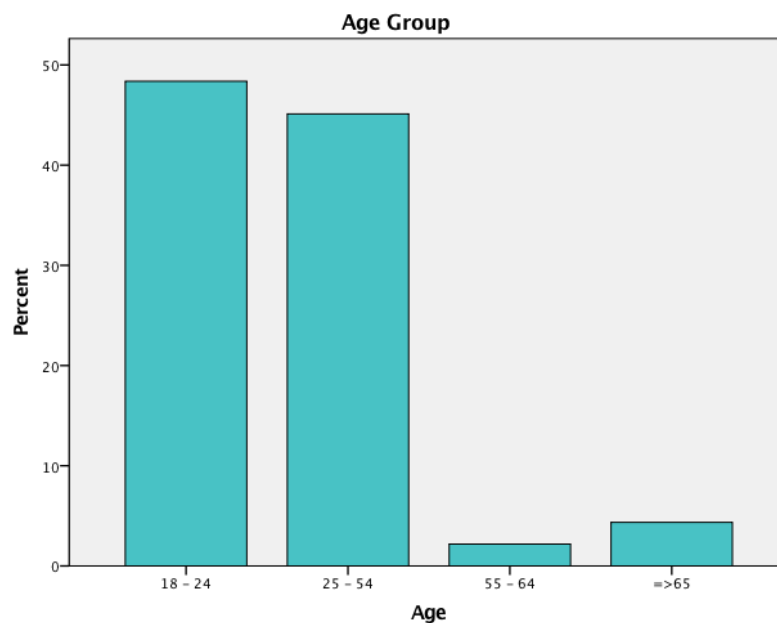


Figure 8 – Presence of DH in the age groups studied

An evaluation of different characteristics of all individuals was carried out, and the summary of the demographic and baseline characteristics of all subjects by treatment is shown in Table V.

Concerning smoking habits, 26,7% (n=8) of the sample population were smokers and 23,3% (n=7) relate to female participants (Figure 9). There is no statistically significant difference between gender and smoking habits according to Pearson Chi-Square significance ($p > 0,419$).

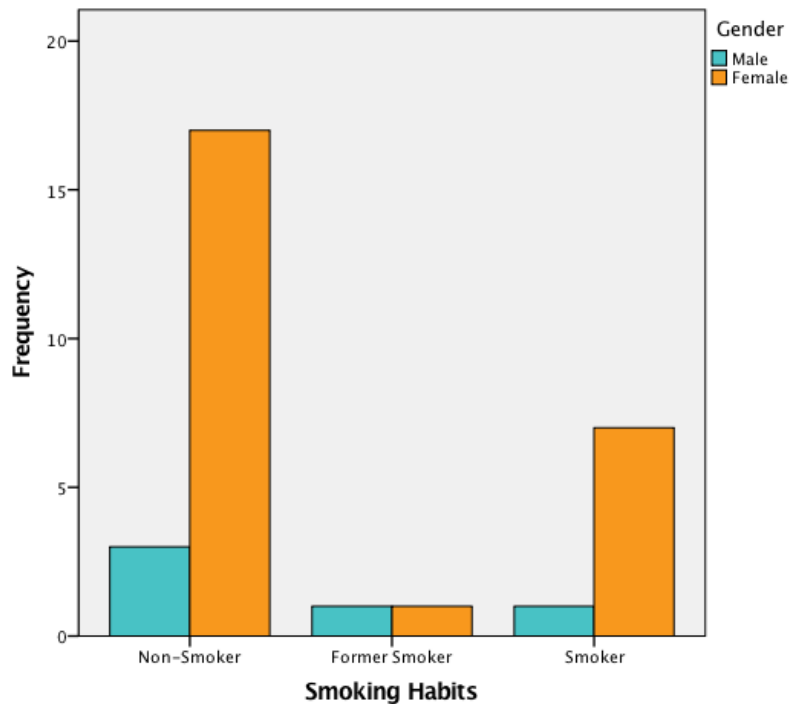


Figure 9 – Smoking Habits

Considering oral hygiene habits, 96,7% (n=29) of the patients reported brushing their teeth more than once a day, while only 3,3% (n=1) brushes once or less a day. Individuals were also asked what type of toothbrush bristles utilize, and 70% (n=20) affirmed the use of medium bristles, while 8 participants (26,7%) have soft or extra-soft options and only 1 participant (3,3%) uses a toothbrush featuring hard/firm bristles (Figure 10). There is no statistically significant difference between both oral hygiene habits and the two study groups (A and B) according to Pearson Chi-Square significance ($p > 0,334$).

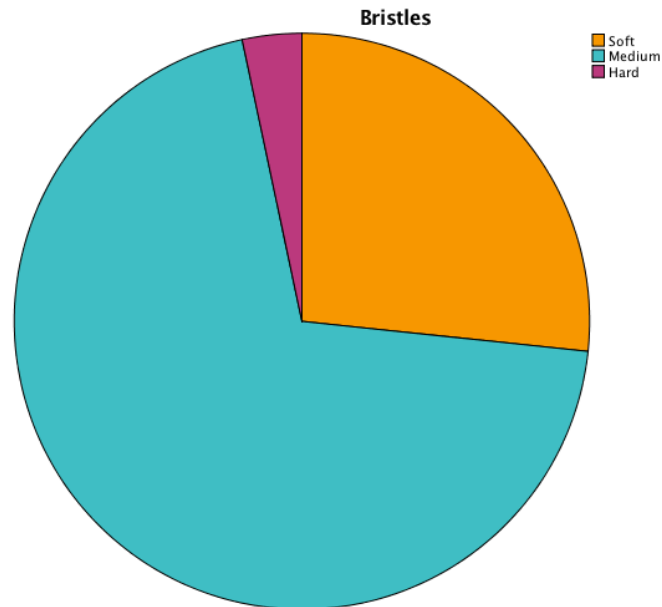


Figure 10 – Type of bristles used among participants

Regarding the use of complementary methods to improve oral hygiene, 25 individuals (83,3%) affirmed having the regular use of dental floss/interdental brushes, while 16,7% (n=5) do not use any other technique other than brushing. Taking a look at both study groups, 76,5% (n=13) of the participants from group B and 92,3% (n=12) from group A have this practice as part of their oral hygiene routine (Figure 11).

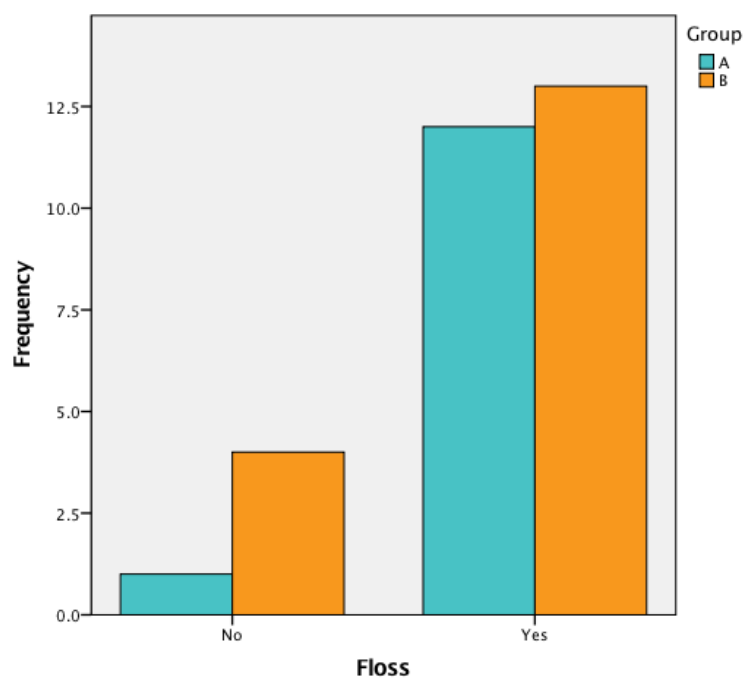


Figure 11 – Flossing Habits

Regarding DH characteristics such as self-reported history by the individual and trigger stimuli, it was established that there is a higher prevalence of pain response to cold stimuli 83,3% (n=25), followed by osmotic – sweet and/or acidic stimuli – 33,3% (n=10), then dental brushing and masticatory pressure/tension with 13,3% (n=4) and hot stimuli with 10% (n=3). On DH antecedents, 5 participants (16,7%) affirmed having symptoms for less than 1 year while the remaining 25 (83,3%) have symptomatology for longer than a year.

In addition, it was found that in the study sample of 30 participants, there is gingival recession in 63,3% (n=19) of the cases (Figure 12).

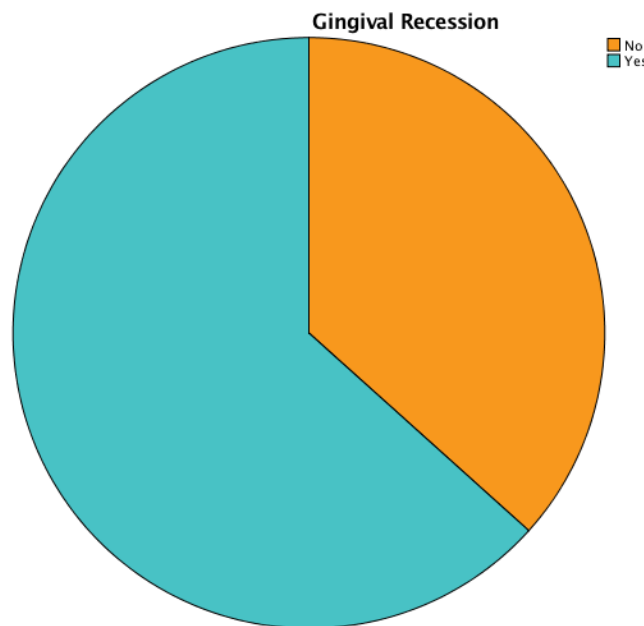


Figure 12 – Prevalence of gingival recession

The vast majority of respondents (70%) referred feeling sensitivity at times, while only 26,7% (n=8) and 3,3% (n=1) reported having pain frequently and permanently, respectively (Figure 13).

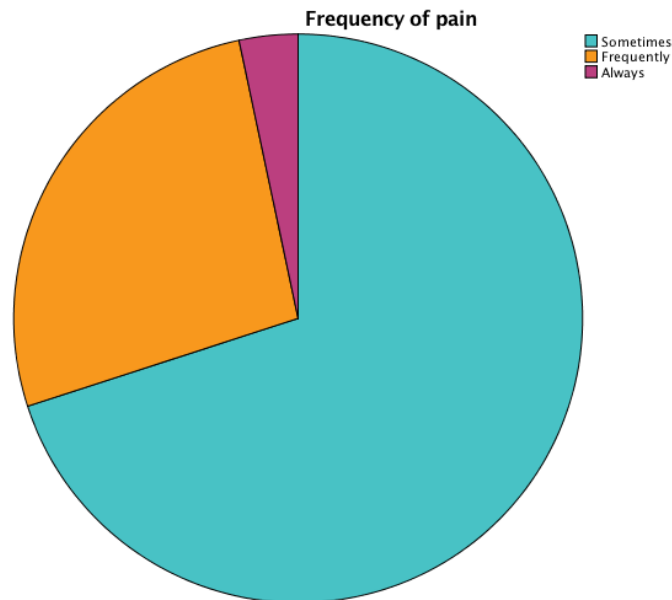


Figure 13 – Frequency of pain

Table V – Demographic and baseline characteristics by treatment group for all subjects

Characteristic	Test group A (n=13)	Test group B (n=17)	Total (n=30)
Age (years) ^a			
Mean	33.77	34.06	31.66
SD	15.74	14.10	13.24
Median	24.00	26.00	25.00
Range	22-70	21-68	21-70
Sex, n (%) ^a			
Male	4 (30.8)	1 (5.9)	16.7
Female	9 (69.2)	16 (94.1)	83.3
Smoker, n (%)			
Yes	3 (23.1)	12 (70.6)	22 (73.3)
No	10 (76.9)	5 (29.4)	8 (26.7)
Hygiene Habits, n (%)			
Brushes <1	0 (0)	1 (5.9)	1 (3.3)
Brushes >1	13 (100)	16 (94.1)	29 (96.7)
Dental Floss			
Yes	3 (23.1)	5 (29.4)	8 (26.7)
No	10 (76.9)	12 (70.6)	22 (73.3)
Bristles, n (%)			
Soft	5 (38.5)	3 (17.6)	8 (26.7)
Medium	8 (61.5)	13 (76.5)	21 (70)
Hard	0 (0)	1 (5.9)	1 (3.3)
History of DH, n (%)			
<1 year	1 (7.7)	4 (23.5)	5 (16.7)
>1 year	12 (92.3)	13 (76.5)	25 (83.3)
Trigger stimuli, n (%)			
Thermal	9 (69.2)	9 (52.9)	18 (60)
Mechanical	0 (0)	0 (0)	0 (0)
Osmotic	1 (7.7)	0 (0)	1 (3.3)
Various	3 (23.1)	8 (47.1)	11 (36.7)
SD, standard deviation			
^a No statistically significant difference was indicated between the two treatment groups with respect to either gender or age ($p > 0,05$)			

The sample involved 184 teeth in total (76 in group A and 108 in group B), and consisted of 59,8% incisors, 14,2% canines, 19% premolars and 7% molars. Table VI depicts the type of teeth included in the study.

Table VI – Teeth included in the study

Type of teeth ^a	Test group A ^a (n=13)	Test group B ^a (n=17)	Total (n=30)
Upper incisor, n (%)	12 (15.8)	25 (23.1)	37 (20.1)
Lower incisors, n (%)	29 (38.2)	44 (40.7)	73 (39.7)
Upper canines, n (%)	4 (5.3)	9 (8.3)	13 (7.1)
Lower canines, n (%)	5 (6.6)	8 (7.4)	13 (7.1)
Upper premolars, n (%)	13 (17.1)	8 (7.4)	21 (11.4)
Lower premolars, n (%)	5 (6.6)	9 (8.3)	14 (7.6)
Upper molars, n (%)	6 (7.9)	3 (2.8)	9 (4.9)
Lower molars, n (%)	2 (2.6)	2 (1.9)	4 (2.1)
^a No statistically significant difference was indicated between the two treatment groups with respect to type of teeth included in the study ($p > 0,05$)			

The teeth included fall within a range of 2 to 8 and on average each participant had 3.99 ± 1.98 teeth included in the clinical trial.

A brief analysis of the association between the pain intensity – gentle, moderate and severe – and past history of DH reported by the participant was carried out. It is observed no statistically significant difference ($p > 0,738$). Analysing the results, summarised in Table VII, we may conclude that 16,7% of the participants in this sample experience symptomatology for more than a year and only a small proportion of the studied population (6,7%) suffers from severe pain.

Table VII – Association between Pain Intensity and DH History

Pain Intensity	How long suffer from DH			Total
	<6 months	>6 months	>1 year	
Gentle	2	9	2	13
Moderate	3	10	2	15
Severe	0	1	1	2
Total	5	20	5	30
No statistically significant difference ($p > 0,05$)				

The association of DH and gender, was also analysed and it was found a statistically significant relationship ($p < 0,008$) between those variables.

III.2 Intervention Analysis

III.2.1 Efficacy Results

In total 184 teeth were screened and the subjects responses of each individual tooth to air-blast and thermal assessments were measured and recorded at baseline, 2-week and 4-week examinations. The results (median values) are shown in Tables VIII.

Table VIII – Within-group comparison of dentine hypersensitivity scores to the two stimuli tests at the three different intervals measured

Treatment Group (n)		Baseline Air-Blast	Baseline Thermal	2 weeks Air-Blast	2 weeks Thermal	4 weeks Air-Blast	4 weeks Thermal
Group A (n=76)							
	Median	5.00	6.00	3.00	5.00	3.00	4.00
	Percentiles						
	25	3.00	4.00	1.00	4.00	2.00	3.00
	50	5.00	6.00	3.00	5.00	3.00	4.00
	75	7.00	8.00	4.00	8.00	4.00	7.00
Group B (n=108)							
	Median	3.00	6.00	4.00	6.00	2.00	4.50
	Percentiles						
	25	2.00	5.00	2.00	3.00	1.00	2.00
	50	3.00	6.00	4.00	6.00	2.00	4.50
	75	7.00	8.00	6.00	8.00	4.00	7.00

Analysing the scores obtained from group A participants, it can be verified that on the baseline evaluation 50% of the participants scored pain up to the value of 5.00 and 6.00 for the evaporative and thermal stimuli, respectively. While group B subjects scored lower on the air-blast evaluation, up to 3.00, but noted the same results on the thermal test.

Concerning the results on the 2-week follow-up, from the participants of group B it is observed that the median value recorded for the air-blast evaluation increased slightly from a value of 3.00 to 4.00. However, it appears to be a reduction for the remaining values, for group A and B.

Regarding the last evaluation performed after 4 weeks, 75% of the participants from group A logged scores up to 4.00 and 7.00 on the air-blast and thermal stimuli, respectively. Similar results have been shown for group B subjects.

Overall, it is observed a reduction in DH scores from baseline to the subsequent follow-up for the two groups, also observed on tables IX and X.

Table IX – Pain Frequency during the 4-weeks treatment for Group A

Pain Score	Baseline Air-Blast n (%)	Baseline Thermal n (%)	2 weeks Air-Blast n (%)	2 weeks Thermal n (%)	4 weeks Air-Blast n (%)	4 weeks Thermal n (%)
0	1 (1.3)	1 (1.3)	9 (11,8)	1 (1,3)	4 (5,3)	3 (3,9)
1	2 (2.6)	1 (1.3)	11 (14,5)	6 (7,9)	11 (14,5)	6 (7,9)
2	1 (1.3)	2 (2.6)	5 (6,6)	1 (1,3)	11 (14,5)	5 (6,6)
3	16 (21.1)	1 (1.3)	29 (38,2)	8 (10,5)	26 (34,2)	12 (15,8)
4	14 (18.4)	16 (21.1)	6 (7,9)	15 (19,7)	10 (13,2)	18 (23,7)
5	7 (9.2)	4 (5.3)	6 (7,9)	10 (13,2)	6 (7,9)	7 (9,2)
6	13 (17.1)	20 (26.3)	3 (3,9)	3 (3,9)	0 (0)	5 (6,6)
7	4 (5.3)	8 (10.5)	0 (0)	6 (7,9)	1 (1,3)	3 (3,9)
8	6 (7.9)	8 (10.5)	3 (3,9)	11 (14,5)	3 (3,9)	4 (5,3)
9	7 (9.2)	5 (6.6)	0 (0)	5 (6,6)	0 (0)	6 (7,9)
10	5 (6.6)	10 (13.2)	4 (5,3)	10 (13,2)	4 (5,3)	7 (9,2)
Total						76 (100)

Table X – Pain Frequency during the 4-weeks treatment for Group B

Pain Score	Baseline Air-Blast n (%)	Baseline Thermal n (%)	2 weeks Air-Blast n (%)	2 weeks Thermal n (%)	4 weeks Air-Blast n (%)	4 weeks Thermal n (%)
0	7 (6.5)	7 (6.5)	12 (11,1)	0 (0)	21 (19,4)	5 (4,6)
1	4 (3.7)	0 (0)	12 (11,1)	2 (1,9)	14 (13,0)	8 (7,4)
2	17 (15.7)	1 (0.9)	22 (20,4)	19 (17,6)	27 (25,0)	19 (17,6)
3	29 (26,9)	6 (5.6)	3 (2,8)	17 (15,7)	10 (9,3)	7 (6,5)
4	3 (2.8)	9 (8.3)	10 (9,3)	7 (6,5)	10 (9,3)	15 (13,9)
5	0 (0)	23 (21.3)	12 (11,1)	6 (5,6)	13 (12,0)	11 (10,2)
6	18 (16.7)	13 (12)	13 (12,0)	8 (7,4)	4 (3,7)	10 (9,3)
7	5 (4.6)	5 (4.6)	8 (7,4)	20 (18,5)	3 (2,8)	15 (13,9)
8	21 (19.4)	23 (21.3)	13 (12,0)	14 (13,0)	6 (5,6)	12 (11,1)
9	0 (0)	15 (13.9)	3 (2,8)	14 (13,0)	0 (0)	5 (4,6)
10	4 (3.7)	6 (5.6)	0 (0)	1 (0,9)	0 (0)	1 (0,9)
Total						108 (100)

III.2.2 Comparison Results Within Study Groups

The non-parametric Friedman test was performed to compare within experimental groups and the time intervals studied. The results are shown on Table XI.

At first, the results from the two groups were analysed individually. For both groups, there is a statistically significant reduction ($p < 0,0005$) in DH scores from baseline to subsequent follow-up examinations.

Table XI – Intra-group comparison of raw means throughout the 4-weeks treatment

Evaluations	Group A (n=76)	Group B (n=108)
<u>Air-blast^a</u>		
Baseline	2.62	2.47
2-weeks	1.64	2.06
4-weeks	1.74	1.47
^a Statistically significant difference ($p < 0,0005$)		
<u>Thermal^a</u>		
Baseline	2.18	2.46
2-weeks	2.12	2.05
4-weeks	1.70	1.49
^a Statistically significant difference ($p < 0,0005$)		

The Wilcoxon test was then applied in order to further analyse the results (Tables XII, XIII and XIV).

Table XII – Intra-group comparison of the variation of responses throughout the time intervals established

Evaluations						
<i><u>Air-Blast</u></i>						
	<u>Negative Ranks^a</u>		<u>Positive Ranks^b</u>		<u>Ties^c</u>	
	A	B	A	B	A	B
Baseline vs. 2 weeks	50	57	5	22	21	29
Baseline vs. 4 weeks	53	76	4	9	19	23
2 weeks vs. 4 weeks	15	52	24	5	37	51
<i><u>Thermal</u></i>						
	<u>Negative Ranks^a</u>		<u>Positive Ranks^b</u>		<u>Ties^c</u>	
	A	B	A	B	A	B
Baseline vs. 2 weeks	28	63	25	27	23	18
Baseline vs. 4 weeks	38	79	13	15	25	14
2 weeks vs. 4 weeks	35	54	14	8	27	46
^a Hypersensitivity reduction in relation to the baseline values						
^b Hypersensitivity increase in relation to the baseline values						
^c Hypersensitivity maintenance in relation to the baseline values						

Table XII corresponds to the differences in DH values of examinations at 2 and 4 weeks compared to baseline results, as well as the second evaluation compared to the final follow-up. The results obtained for negative ranks means the reduction of pain sensitivity whereas the positive ranks account for an increased sensitivity score to painful stimuli. When differences in DH scores did not occur, it was perceived as an indicator of no variation in pain. Both groups showed decreased levels of sensitivity for the duration of the clinical study.

Table XIII – Within-group changes for the time intervals established - Group A

Evaluations			
<u>Air-Blast</u>			
	Z	Asymp. Sig (1-tailed)	p-value*
Baseline vs. 2 weeks	-5,968	0,00025	0,00075
Baseline vs. 4 weeks	-6,105	0,00025	0,00075
2 weeks vs. 4 weeks	-0,949	0,1715	0,5145
<u>Thermal</u>			
	Z	Asymp. Sig (1-tailed)	p-value*
Baseline vs. 2 weeks	-1,255	0,1045	0,3135
Baseline vs. 4 weeks	-4,033	0,00025	0,00075
2 weeks vs. 4 weeks	-3,538	0,00025	0,00075
* Bonferroni adjustment based upon the three comparisons			

According to the results illustrated on table XIII concerning the participants of group A, significant differences were observed from baseline scores to the air-blast assessment for the two following revaluations. However, there is not a significant reduction from the 2-week to the 4-week of product use.

For the thermal stimuli scores, there was not a significant reduction in sensitivity values on the first two weeks of product use nonetheless a significant desensitizer effect was noticed for the following evaluation.

Table XIV – Within-group changes for the time intervals established - Group B

Evaluations			
<u>Air-Blast</u>			
	Z	Asymp. Sig (1-tailed)	p-value*
Baseline vs. 2 weeks	-2,646	0,004	0,012
Baseline vs. 4 weeks	-6,417	0,00025	0,00075
2 weeks vs. 4 weeks	-5,787	0,00025	0,00075
<u>Thermal</u>			
	Z	Asymp. Sig (1-tailed)	p-value*
Baseline vs. 2 weeks	-3,253	0,0005	0,0015
Baseline vs. 4 weeks	-5,723	0,00025	0,00075
2 weeks vs. 4 weeks	-5,089	0,00025	0,00075
* Bonferroni adjustment based upon the three comparisons			

Participants from group B exhibited a statistically significant improvement for both air-blast and thermal stimuli scores in all evaluations, as depicted on table XIV.

III.2.3 Comparison Results Between Study Groups

To assess the efficacy of the two different dentifrices and compare its performance, the U Mann-Whitney test was applied (Table XV).

On the evaluation performed at baseline the two groups were evenly balanced with no statistically significant differences for the thermal values obtained, however it is noticed a statistically significant difference with respect to the air-blast assessment.

The following evaluations resulted in no statistically significant differences between the two test groups.

Table XV – Inter-group comparisons for air-blast and thermal scores

<i>Air-Blast</i>			
	Z	Asymp. Sig (2-tailed)	
Baseline	-2,545	0,011	
	Z	Asymp. Sig (1-tailed)	p-value*
2 weeks	-1,772	0,038	0,114
4 weeks	-1.906	0,0285	0,0855
<i>Thermal</i>			
	Z	Asymp. Sig (2-tailed)	
Baseline	-0,099	0,921	
	Z	Asymp. Sig (1-tailed)	p-value*
2 weeks	-0.996	0,1595	0,4785
4 weeks	-0,755	0,3775	1,1325
* Bonferroni adjustment based upon the three comparisons			

III.3 Adverse Events reported

Five participants reported five AEs during the study. All were associated with the Group-A dentifrice and were of very mild severity oral events (dysgeusia and/or tingling tongue in all five cases). No serious AEs, incidents or oral soft tissue abnormalities were observed.

IV. Discussion

The option for this study's theme was based on the fact that, despite being considerably prevalent in today's society, DH is not seen as a pathology but considered as a condition to which the individual is attached to. Even though the number of patients suffering from DH is high and increasing, the dental clinicians continue to demonstrate lack of knowledge regarding aetiology and pathophysiology which prevents them to provide the most adequate treatment, acting recurrently based on unawareness. Knowing that DH is predominantly caused by intraoral causes as well as influenced by oral environment – acidic conditions –, the dentist attains a central role in the prevention and treatment of this pathology capable of causing social and psychological consequences to the individuals.

Numerous strategies have been developed for the treatment of DH. Some emphasize the employment of active DH management, which entails the application of desensitizing dentifrices, which are recommended as the initial therapy approach and in most cases, considered the most appropriate method. In the most severe cases is recommended a complete DH management, consisting of at-home and in-office therapies ^(2, 5, 7, 11). One must stress that of all the proposed treatments, none has been proven to be the ultimate or the permanent cure for DH.

All treatment options fall into two types of action mechanisms. The first involves the blockage of the nerve transmission to the pulp – nerve stabilisation/desensitisation –, and the second method concerns the physical occlusion and/or reduction of the diameter of the exposed dentinal tubules ^(6, 7, 11-13, 15). Dentinal occlusion may be achieved by two different means, either by the deposition of an occluding layer on top of the dentine or the infiltration of the occluding material into the dentinal tubules – plugs. Insoluble salts usually form a thin aggregate on the dentine and as a result, these therapies are more effective in the reduction of DH than in the formation of a precipitate with the purpose of tubules occlusion ^(1, 9, 17, 18).

Dentifrices are an excellent mean of delivery of desensitizing particles of which n-HA stands out as one of the most biocompatible and bioactive materials, introduced to stimulate intratubular mineralisation ^(1, 16). Appropriately, the objective of this randomized clinical study was to evaluate the effectiveness of n-HA based dentifrice on reducing DH after a 4-week period, compared to standard fluoridated toothpaste.

The prevalence acquired among the patients selected was 37.2% (n=42). Even though this value is lower than predicted, possibly due to a small sample – not all patients attending appointments at the Faculty's clinic were interviewed therefore were not included in the statistics –, it is inside the prevalence range found in the literature, which corresponds to 4-57% ⁽⁸⁻¹¹⁾. Another explanation could be the fact that DH is stimulated and consequently patients tend to develop an adaptive behaviour as they eventually try to avoid certain stimuli. Regardless this estimation is of little scientific value and cannot be inferred to the population.

From the analysis of the sociodemographic variables of the interviewed population (n=113), it was found a statistically significant relationship between the variables DH and gender, supporting the hypotheses that female individuals have a higher likelihood of experiencing DH, which supports previous studies ^(12, 19-23). It is noteworthy that the result obtained may lie on the fact that a greater number of female patients have been approached regarding the symptomatology of DH however there may actually be statistical differences in the prevalence of DH depending on gender as the aetiological factors in each gender present variability and can lead to divergent patterns of some predisposing factors such as tooth erosion ⁽⁵⁾.

The presence of comorbidities is quite frequent (35.4%) specially in the older population and, for that reason, participants with uncontrolled systemic illnesses

and/or individuals that began a sort of medication within one month prior to the start of the study or during the course of the study were excluded as this medication can affect pain perception and skew the results.

The age range included in this study is extensive, 21-70 years old. Nonetheless the age group most associated with DH was between 18-24 years old. This may be related with the context of the sample as most volunteers were within younger age groups. It could also be associated with the fact that youngsters are the target patients for specific dental treatments, such as teeth whitening as well as the fact that DH symptomatology has the tendency to diminish with age progression due to phenomena such as continuous deposition of dentine – secondary and tertiary – which cause obliteration of dentinal tubules and also pulp atrophy ⁽²³⁾. This finding, however, does not agree with other studies that affirm a higher prevalence in the age group of 35-49 years old ^(17, 19, 23).

According to the data obtained in the present study, the most DH affected teeth verified are the lower incisors (39.7%), followed by the upper incisors (20.1%) and upper premolars (11.4%). Kumari M., *et al.*, 2013 ⁽¹⁰⁾, Mehta D., *et al.*, 2014 ⁽²⁰⁾ and Freitas S., *et al.*, 2014 ⁽²⁴⁾ established a higher frequency of DH on upper canines (12.5%) and lower premolars (11.1%). However, there is a wide discrepancy of results in the prevalence of affected teeth, which may be due to different causes, such as the presence of predisposing factors – age, history of dental treatments – or due to different evaluation methods.

Concerning smoking habits, only 26.7% of the sample population were smokers and 23.3% relate to female participants. Once more, this result may reflect the higher number of female patients that have been interviewed. In the Sharma D, *et al.*, 2013 ⁽²⁵⁾ study, most subjects were non-smokers supporting the findings in the present study. On the contrary, Costa R., *et al.*, 2014 ⁽²³⁾ suggested a

higher association between smokers and a greater number of teeth affected with DH, considering this variable as a risk indicator. The contradictory findings may be due to the lack of research assessing the effect smoking behaviour may have on DH.

Considering oral hygiene habits, 86.7% of the patients reported brushing their teeth more than once daily, as well as the vast majority (70%) revealed the use of medium bristles. These results show no statistically significant difference between the two variables and the incidence of DH, therefore there is no indication these characteristics may lead to a higher risk of having DH.

Gingival recession was found in 63.3% of the sample population, result corroborated by different studies that presented this condition as the enabler to dentine exposure and one of the strongest risk indicators of DH ^(1, 23).

Concerning the questions posed to the interviewed individuals, for instance, on oral hygiene and smoking habits, one can raise the problem of veracity and accuracy of responses by the constraints of the respondents.

Aiming to compare the ability to reduce or relief pain of DH over a brief period of time, the present clinical study has proven that the two regiments tested were effective in reducing DH as both achieved similar improvements in the short-term observation, albeit only few participants reported the complete absence of pain. Intra-group improvements in pain relief were demonstrated by reductions across all clinical evaluations scores over the designated intervals, for both groups. In almost all instances the changes detected within each group were towards the management and/or pain alleviation.

Taking a look at the baseline values, it is perceptible that Group A had slightly higher scores for the evaporative evaluation, which have proven to be significantly different ($p < 0,05$), as it is demonstrated on table XV, averting the

comparison between groups on these assessment. This evidence may also raise the question about the effectiveness of the randomization process and/or suggest a recruitment bias. Nevertheless, pondering on the fact that the non-parametric test used – U Mann-Whitney – is designed for small samples might explain the outcome acquired.

The analyses of inter-group efficacy between the two treatment options was considered of primary interest in order to attempt to determine superiority of one dentifrice over another over time. In this study, however, those results were not obtained.

The unexpected efficacy of the placebo group (B) – negative control – may result from two plausible reasons. First, due to the subjectivity of pain, the placebo effect produces an effect on clinical studies as it influences the individuals' pain response, possibly due to complex psychological and physiologic interactions ^(15, 16, 21), and may contribute to unforeseen and conflicting findings. Subsequently, we should acknowledge that the effect evaluated is cumulative, hence the participants compliance is required. Confounding factors such as dietary habits – consumption of acidic beverages – and traumatic brushing techniques should be diagnosed during anamnesis and altered during the investigation to enhance the therapeutic approach.

Certain studies reported no differences between regular fluoridated toothpastes and active-ingredients desensitizing dentifrices ^(1, 26, 27). The ability to form insoluble precipitates that may occlude the dentinal tubules ^(16, 24) accounts for the recommendation of fluoride as one of the substance to be used for the management of DH and may explain the efficacy on pain relief in the experimental group B.

Evaluation of the therapy options for DH is a demanding task, since both placebo effect and the biological desensitization over time may confound or concur with the clinical results. Also, it is necessary to assume pain as a highly subjective matter and, consequently, difficult to quantify, and because of the imprecision inherent to this method of measurement two well-recognized stimuli assessments were performed rating tooth sensitivity in a numerical VAS of pain as its validity and reliability have been demonstrated for experimental and clinical trials and it is easy to apply and comprehend ^(28, 29).

The type of stimulus can influence the painful response thereby the applied tests were from the least distressing – air-blast – to the most painful – thermal. In order to minimize interactions within stimuli an adequate period of time – approx. five minutes ^(30, 31) – between applications should be respected, which in some occasions was not complied and might have skewed the results.

Although most of the results are corroborated by the literature there are a few weaknesses presented in this clinical study worth discussing. Firstly, the main investigator was the only examiner collecting the clinical data. Despite the reported positive results over the 4-week interval, more studies are required to help to determine the effect in the long term, not disregarding the variables that might affect the outcome, as from dietary habits and brushing technique that should be monitored. Also, because the study sample was considered relatively small, one may hypothesized that the statistical power was insufficient to produce acceptable results to infer conclusions to the general population.

There has been constant innovation of the therapeutics towards achieving greater efficacy. They aim to increase the comfort and satisfaction in the long term, enabling a better quality of life for the patients. The professional approach to the treatment of DH should always be attentive of the etiologic and existing

predisposing factors, and is up to the clinical to be observant of the various pathologies that may be associated with the symptomatology of DH, in order to diagnose, intervene with the most appropriate therapy and, if possible, avoid the development of this condition through essential care. It is also extremely important to inform and demystify all acquired concepts concerning DH to the general dental clinics and the patients making both conscientious of the importance of this depreciative condition.

Having served as a pilot study, the limitations mentioned throughout this discussion should be controlled in an upcoming study. With the adequate changes in the research protocol, this can and should be applied on a large scale, as it will certainly provide more valuable and reliable information.

V. Conclusion

Under these experimental conditions and within the limitations of the present study, it was concluded that the prevalence of DH among the sample selected was found within the range described in the literature, female individuals are more likely to experience DH than males and the age group most affected is between 18 and 24 years old. Several stimuli may trigger a painful response, though the cold stimuli is the most commonly reported amongst the present study's individuals. Furthermore, the most affected teeth registered were the incisors followed by the upper premolars and more than 63% of the subjects presented gingival recession.

Considering various characteristics, such as smoking and oral hygiene habits, no association could be established. Consequently, those features cannot be implicated as higher risk indicators for the manifestation of DH.

Both investigated treatments have promising desensitizing potential based on the different described mechanisms of action. When compared among them, in the time intervals established, all proven to be equally effective and clinical significant superiority of one toothpaste over the other was not proven. Therefore, it is reasonable to conclude that both dentifrices are clinically comparable and efficient for the management and reduction of DH.

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VII. Appendixes

Appendix I

Explicação do Estudo



Monografia de Investigação do Mestrado Integrado em Medicina Dentária

Faculdade de Medicina Dentária da Universidade do Porto

Ano Letivo: 2016/2017

PROJETO DE INVESTIGAÇÃO

Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

EXPLICAÇÃO DO ESTUDO

Investigadora Principal: Raquel Sofia Brandão de Carvalho, Estudante MIMD
raquelsbcarvalho@gmail.com

Orientador: Professor Doutor Paulo Rui Galvão Ribeiro de Melo,
Professor Associado da Faculdade de Medicina Dentária da Universidade do Porto

Objetivos da investigação:

Convidamo-lo(a) a participar neste estudo “Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante” como voluntário(a) e sem compensação monetária.

Este projeto de investigação tem como objetivo avaliar a eficácia de uma pasta dentífrica à base de Nano-Hidroxiapatite na redução da Hipersensibilidade Dentinária.

Metodologia:

Numa primeira fase do projeto, será distribuído um questionário aos pacientes da Faculdade de Medicina Dentária da Universidade do Porto.

Finda esta primeira etapa, os primeiros 50 potenciais participantes que satisfaçam os critérios de inclusão/exclusão e assinem o consentimento informado serão elegidos para participar no estudo supracitado. Neste seguimento, será realizado exame clínico às peças dentárias, aos tecidos moles e duros e, será solicitado o preenchimento de um questionário que diz respeito à dor associada à Hipersensibilidade Dentinária.

Os participantes deste estudo serão divididos por dois grupos.

Grupo A: administração de dentífrico à base de Nano-Hidroxiapatite

Grupo B: grupo de controlo

Posteriormente, serão agendadas avaliações/aplicações 2, 4, 6 e 8 semanas após o uso de produto, que serão efetuadas por um examinador clínico diferente.

Resultados/Benefícios esperados:

Esta investigação intende informar os pacientes dos diversos tratamentos disponíveis, como prevenir o aparecimento de novas alterações e diminuir a evolução das complicações existentes e, ainda, consciencializar para a importância da saúde oral e do acompanhamento frequente pelo Médico Dentista.

Riscos/desconforto:

No que respeita aos riscos associados o presente estudo clínico não prevê qualquer risco/desconforto para os seus participantes. O possível desconforto será o inerente ao preenchimento de um questionário e ao exame clínico seguido da aplicação do produto.

Características éticas:

A realização deste estudo clínico está sujeita ao preenchimento de consentimento informado pelo participante. Caberá à investigadora principal esclarecer qualquer dúvida, referindo o âmbito do trabalho do estudo. O participante pode aceitar ou recusar participar no presente estudo clínico e revogar o consentimento de participar a qualquer momento. A confidencialidade dos dados e o anonimato dos participantes encontra-se assegurada. Esta investigação não tem quaisquer fins financeiros ou económicos, sendo meramente académica.

Declaro que recebi, li e compreendi a explicação que me foi fornecida, por escrito e verbalmente, acerca da presente investigação e que me foram respondidas todas as questões que julguei necessárias. Nestas circunstâncias aceito participar neste projeto.

Nome Completo: _____

Assinatura: _____

____/____/____

(Raquel Sofia Brandão de Carvalho)

Appendix II

Declaração de consentimento informado

DECLARAÇÃO DE CONSENTIMENTO INFORMADO

Título: Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

Eu, _____ (nome completo), BI/CC nº: _____ compreendi a explicação que me foi fornecida, por escrito e verbalmente, acerca da investigação que será conduzida pela Estudante Raquel Sofia Brandão de Carvalho da Faculdade de Medicina Dentária da Universidade do Porto, para qual é pedida a minha participação. Foi-me dada oportunidade de fazer as perguntas que julguei necessárias, e para todas obtive resposta satisfatória.

Tomei conhecimento de que, de acordo com as recomendações da Declaração de Helsínquia, a informação que me foi prestada versou os objetivos, os métodos, os benefícios previstos, os riscos potenciais e o eventual desconforto. Além disso, foi-me afirmado que tenho o direito de decidir livremente aceitar ou recusar a todo o tempo a minha participação no estudo. Sei que posso abandonar o estudo e que não terei que suportar qualquer penalização, nem quaisquer despesas pela participação neste estudo.

Foi-me dado todo o tempo de que necessitei para refletir sobre esta proposta de participação.

Nestas circunstâncias, consinto participar neste projeto de investigação, tal como me foi apresentado pela investigadora responsável sabendo que a confidencialidade dos participantes e dos dados a eles referentes se encontra assegurada.

Mais autorizo que os dados deste estudo sejam utilizados para este e outros trabalhos científicos, desde que irreversivelmente anonimizados.

Data: __/__/____

Assinatura do paciente:

O/A Investigador(a):

Dados de contacto: **raquelsbcarvalho@gmail.com**

O/A Orientador(a):

Appendix III

Questionário



Monografia de Investigação do Mestrado Integrado em Medicina Dentária

Faculdade de Medicina Dentária da Universidade do Porto

Ano Letivo: 2016/2017

PROJETO DE INVESTIGAÇÃO

Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

QUESTIONÁRIO

Caro(a) Participante:

O presente questionário destina-se à recolha de dados para seleção de candidatos a participar num caso estudo sobre Hipersensibilidade Dentinária.

Apresenta-se dividido em duas partes. A Parte I consiste num questionário dirigido à história clínica do paciente, sendo que a Parte II diz respeito ao exame clínico das peças dentárias envolvidas devendo ser preenchido pelo examinador clínico.

A devida análise e conclusão do questionário terá uma duração aproximada de dez minutos, devendo ser preenchido nas consultas realizadas na clínica da FMDUP do corrente ano letivo.

Obrigada pela participação.

Código do paciente: _____

Sexo: M ☐ F ☐

Idade: _____

Data: _____

Parte I: História Clínica

1. Está em tratamento médico?

☐ Sim. Discriminar: _____

☐ Não

2. Toma alguma medicação?

☐ Sim. Discriminar: _____

☐ Não

3. Tem alergias?

☐ Sim. Discriminar: _____

☐ Não

4. Patologia Sistémica:

☐ Cardiovascular: _____

☐ Respiratória: _____

☐ Gastrointestinal: _____

☐ Renal: _____

☐ Hematológica: _____

☐ Imunológica: _____

☐ Nervosa: _____

☐ Endócrina e Metabólica: _____

☐ Óssea, Muscular e Articular: _____

☐ Genética: _____

☐ Infeciosa: _____

☐ Outra: _____

5. Está grávida?

- ☐ Sim. N° de Meses: _____
☐ Não

6. Hábitos Tabágicos

- ☐ Nunca fumou
☐ Fumador. N° Cigarros/dia: _____
☐ Ex-Fumador

7. Escova os dentes regularmente?

- ☐ Sim. Quantas vezes: _____
☐ Não

8. Tipo de escova:

- ☐ Manual
☐ Elétrica

9. Qual é a dureza da sua escova de dentes?

- ☐ Mole
☐ Média
☐ Dura

10. Usa escovilhão e/ou fita/fio dentária?

- ☐ Sim. Com que frequência? _____
☐ Não

11. Realizou algum tratamento dentário recentemente?

- ☐ Sim. Qual: _____
☐ Não

12. Apresenta/apresentou sintomas de sensibilidade dentária previamente a algum tratamento dentário?

- ☐ Sim. Qual: _____
☐ Não

13. Há quanto tempo apresenta sintomas de Hipersensibilidade Dentinária?

14. Como classifica a intensidade de dor que sente/sentiu?

- ☐ Leve
- ☐ Moderada
- ☐ Elevada

15. Quando sente/sentiu Hipersensibilidade Dentinária?

- ☐ Nunca
- ☐ Às vezes
- ☐ Frequentemente
- ☐ Sempre

16. Já se sentiu impedido(a) de exercer alguma atividade devido à Hipersensibilidade Dentinária?

- ☐ Nunca
- ☐ Ocasionalmente
- ☐ Frequentemente
- ☐ Sempre

17. Sente/sentiu sensibilidade com:

- ☐ Frio
- ☐ Calor
- ☐ Escovagem
- ☐ Alimentos Ácidos
- ☐ Outros. Quais: _____

18. Já visitou o Médico Dentista devido à Hipersensibilidade Dentinária?

☐ Sim

☐ Não

19. Fez ou está a fazer tratamento para a Hipersensibilidade Dentinária?

☐ Sim

☐ Não

[Se não, prosseguir para Parte II]

20. Realiza/realizou tratamento onde?

☐ Casa

☐ Consultório

21. Que forma de tratamento realizou?

☐ Dentífrico dessensibilizante

☐ Aplicação de Flúor (Tópica, Verniz, ...)

☐ Restauração dentária

☐ Tratamento Cirúrgico

☐ Laser

☐ Endodontia

☐ Não sabe

22. Durante o tratamento sentiu:

☐ Redução dos sintomas

☐ Eliminação dos sintomas

☐ Não sentiu alterações

23. Após o tratamento sentiu:

☐ Redução dos sintomas

☐ Eliminação dos sintomas

☐ Não sentiu alterações

Parte II: Exame Clínico

1. Quais os dentes afetados pela Hipersensibilidade Dentinária?

2. Indique o número total de dentes afetados:

3. O(s) dente(s) afetado(s) foram submetidos a algum tratamento?

☐ Sim. Qual? Foi usado algum material restaurador?

☐ Não

4. O(s) dente(s) afetado(s) apresentam recessão gengival?

☐ Sim

☐ Não

Obrigada pela colaboração!

Appendix IV

Avaliação pós-utilização



Monografia de Investigação do Mestrado Integrado em Medicina Dentária

Faculdade de Medicina Dentária da Universidade do Porto

Ano Letivo: 2016/2017

PROJETO DE INVESTIGAÇÃO

Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

AVALIAÇÃO DA HIPERSENSIBILIDADE DENTINÁRIA

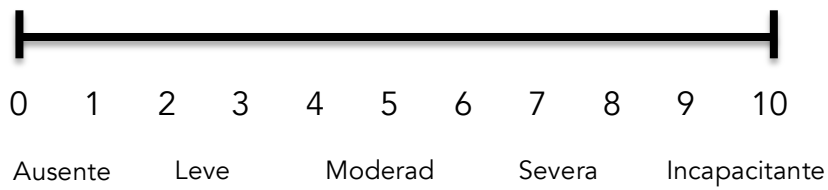
<p>Identificação do Participante</p> <p>Nº _____</p> <p>Data: __/__/____</p>

Instruções:

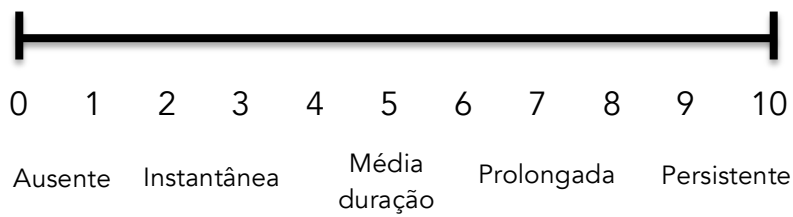
Por favor indique o seu nível de dor provocado por hipersensibilidade dentinária, assinalando na escala o que melhor representa o seu estado atual.

Obrigada pela sua participação.

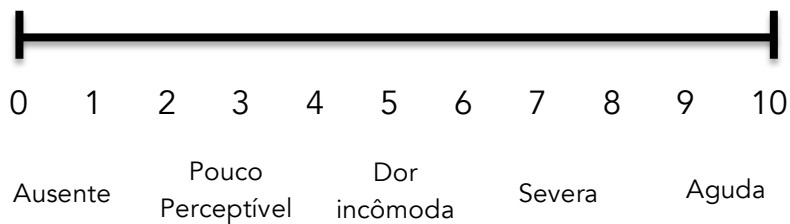
1. Grau de dor



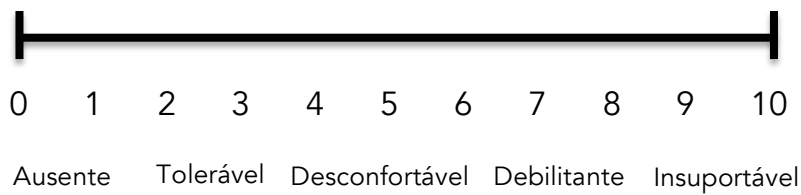
2. Duração da dor



3. Intensidade da dor



4. Tolerância à dor



5. Descrição da dor



Appendix V

Avaliação de Hipersensibilidade (air-blast e thermal)



Monografia de Investigação do Mestrado Integrado em Medicina Dentária

Faculdade de Medicina Dentária da Universidade do Porto

Ano Letivo: 2016/2017

PROJETO DE INVESTIGAÇÃO

Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

AVALIAÇÃO DA HIPERSENSIBILIDADE DENTINÁRIA

<p>Identificação do Participante</p> <p>Nº ____</p> <p>Data: ____/____/____</p>

Instruções:

Por favor indique o seu nível de dor provocado por hipersensibilidade dentinária, assinalando na escala o que melhor representa o seu estado atual.

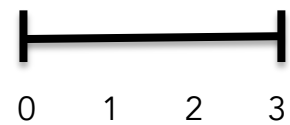
Obrigada pela sua participação.

Pre-application

Air-Blast Assessment:



Schiff Assessment



Teeth	Score	Teeth	Score

Thermal Assessment:



Teeth	Score	Teeth	Score

Efeitos Colaterais?

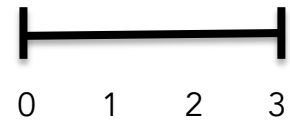
- ☐ Sim. Discriminar: _____
- ☐ Não

Post-application

Air-Blast Assessment:



Schiff Assessment



Teeth	Score	Teeth	Score

Thermal Assessment:



Teeth	Score	Teeth	Score

Efeitos Colaterais?

- ☐ Sim. Discriminar: _____
- ☐ Não

Appendix VI

Cuidados a ter



Monografia de Investigação do Mestrado Integrado em Medicina Dentária

Faculdade de Medicina Dentária da Universidade do Porto

Ano Letivo: 2016/2017

PROJETO DE INVESTIGAÇÃO

Controlo da Hipersensibilidade Dentinária: Estudo clínico a investigar a eficácia de um dentífrico dessensibilizante

CUIDADOS A TER

Após a aplicação do produto:

- Não deve comer ou beber durante 30 minutos após o procedimento;
- Evitar bebidas quentes, produtos que contenham álcool (ex. vinho), comida dura ou pegajosa pelo menos durante 4 horas após o procedimento.

Nos dias de avaliação (Follow-up):

- Deve abster-se de mastigar chiclete durante 8 horas, e comer e beber durante 4 horas;
- Deve abster-se de utilizar colutórios/elixires como meios auxiliares de higiene durante o curso da investigação;
- Não existem outras restrições de dieta ou hábitos tabágicos.

Appendix VII

Parecer da Comissão de Ética

Exm^a Senhora

Estudante **Raquel Sofia Brandão de Carvalho**

000028

Curso de Mestrado Integrado em Medicina Dentária da
Faculdade de Medicina Dentária da U. Porto

10 -01- 2017

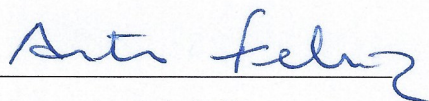
(CC ao Orientador Sr. Prof. Doutor Paulo Rui Galvão Ribeiro de Melo)

Assunto: - Análise do **Projeto de Investigação**, da Estudante Raquel Sofia Brandão de Carvalho, intitulado: "Dentin hypersensitivity management: a clinical study investigating the efficacy of a desensitizing dentifrice", a realizar no âmbito da UC "Monografia de Investigação/Relatório de Atividade Clínica" do Mestrado Integrado em Medicina Dentária da Faculdade de Medicina Dentária da U. Porto, orientado pelo Senhor Professor Doutor Paulo Rui Galvão Ribeiro de Melo.

Informo V. Exa. que o projeto supra citado foi:

- **Aprovado**, na reunião da Comissão de Ética do dia 9 de janeiro de 2017.

Com os melhores cumprimentos,
O Presidente da Comissão de Ética



António Felino
(Professor Catedrático)

Appendix VIII

Declaração de Autoria



Declaração

Monografia de Investigação/Relatório de Atividade Clínica

Declaro que o presente trabalho, no âmbito da Monografia de Investigação/Relatório de Atividade Clínica, integrado no MIMD, da FMDUP, é da minha autoria e todas as fontes foram devidamente referenciadas.

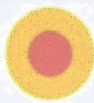
Porto, 7 de Julho de 2017

A handwritten signature in black ink, which appears to read "Raquel Sofia Brandão de Carvalho", is written over a horizontal line.

(A investigadora, Raquel Sofia Brandão de Carvalho)

Appendix IX

Parecer do Orientador



Parecer

(Entrega do trabalho final de Monografia)

Informo que o Trabalho de Monografia desenvolvido pela estudante **Raquel Sofia Brandão de Carvalho**, com o título "**DENTIN HYPERSENSITIVITY MANAGEMENT: A Clinical Study Investigating The Efficacy Of A Desensitizing Dentifrice**" está de acordo com as regras estipuladas pela FMDUP, foi por mim conferido e encontra-se em condições de ser apresentado em provas públicas.

Porto, 7 de Julho de 2017

(O orientador, Professor Doutor Paulo Rui Galvão Ribeiro de Melo)